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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/828,470	04/06/2001	Richard W. Layne	1759.17208-FOR	6760
26308	7590	07/26/2005	EXAMINER	
RYAN KROMHOLZ & MANION, S.C. POST OFFICE BOX 26618 MILWAUKEE, WI 53226			RAGONESE, ANDREA M	
		ART UNIT	PAPER NUMBER	
		3743		

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/828,470	LAYNE ET AL.
	Examiner Andrea M. Ragonese	Art Unit 3743

TWA

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 18 April 2005.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,3,4,11,12 and 22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,3,4,11,12 and 22 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 09/23/2004.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 18, 2005 has been entered.

Response to Amendment

2. The amendment filed on April 18, 2005 has been entered. Examiner acknowledges that **claims 1, 3 and 11** have been amended, **claims 2, 5-10 and 13-21** have been canceled and **claim 22** has been added. Subsequently, **claims 1, 3, 4, 11, 12 and 22** are under consideration.

Response to Arguments

3. Applicant's arguments with respect to **claims 1, 3, 4, 11 and 12** have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. **Claims 1, 3, 4, 11, 12 and 22** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,726,691 B2 and claim 14 of U.S. Patent No. 6,716,216 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they all claim methods comprising the steps of creating a cavity in an area of cancellous bone, compressing at least a portion of the cancellous bone and a filling a portion of the cavity with filler material.

6. **Claims 1, 3, 4, 11, 12 and 22** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-19 of copending Application No. 10/848,514; claims 1-12 of copending Application No. 10/784,392; claims 18-31 of copending Application No. 10/630,519; claims 1-15 of copending Application No. 10/397,049; and claims 30-40 of copending

Application No. 10/346,618. Although the conflicting claims are not identical, they are not patentably distinct from each other because they all claim methods comprising the steps of creating a cavity in an area of cancellous bone, compressing at least a portion of the cancellous bone and a filling a portion of the cavity with filler material.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first and second paragraphs of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claims 1, 3, 4, 11, 12 and 22** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No amendment may introduce new matter into the disclosure of an application after its filing date. See MPEP § 608.04. Specifically, **claim 1** now recites the claim limitations "a wall that peripherally extends...about the elongated axis" in lines 4-7, "to form a void in the cancellous bone" in line 9, "positioning the elongated platform...within the bone" in lines 12-13, and "forming a void...that directs entire expansion" in lines 14-16; however, the originally filed disclosure does not provide evidence that Applicant

possessed the newly claimed invention at the time the application was filed. There is no specific recitation or support for any of these recitations; and therefore, the subject matter added to **claim 1** is considered new matter and must be canceled from the claim(s).

In addition, **claims 3, 4, 11 and 12** contain subject matter, which was not adequately described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, that Applicant had possession of the claimed invention. Thus the specification, as originally filed, lacks proper written description to support of the metes and bounds of the claim limitations.

9. **Claims 1, 3, 4, 11, 12 and 22** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitations "another region" in **claim 1** and "the other region" in **claims 1 and 3** render the claims vague and indefinite for not clearly and distinctly referring to the regions in a manner adequate for one of ordinary skill in the art to understand to which region is being referred.

In addition, **claim 1** recites the limitation "the expandable body" in lines 8-9. There is insufficient antecedent basis for this limitation in the claim.

10. Any rejections in this Office action have been made by applying any pertinent prior art in the field to the merits of the claimed invention as best understood by the Examiner.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. **Claims 1, 3, 4, 11, 12 and 22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchosky (US 6,582,446 B1) in view of Reiley et al. (US 5,827,289).

Marchosky discloses a method inherent in the use of an apparatus, as shown in Figures 12-13, comprising:

providing a tool **100** having an elongated axis, the tool comprising a body **22** that extends along the elongated axis and includes a wall that peripherally extends completely about the elongated axis and terminates at a distal end, the tool also comprising a projection that extends outward beyond the distal end of the body along the elongated axis and that forms an elongated platform **26** that peripherally extends less than completely about the elongated axis;

providing an expandable structure **108** having a longitudinal axis, the expandable structure being sized and configured, upon expansion, to form a void in bone **B**;

introducing the tool **100** and the expandable structure **108** into a bone **B**;

positioning the elongated platform **26** along the longitudinal axis of the expandable structure **108** between the expandable structure **108** and a region of the bone; and

forming a void in another region of the bone with the bone by expanding the expandable structure **108** with the elongated platform **26** positioned that fully capable of serving as an expansion barrier that directs entire expansion of the expandable structure **108** away from the elongated platform **26** and toward the other region of the bone.

Marchosky discloses a method inherent in the use of an apparatus comprising all the limitations recited in **claims 1, 3, 4, 11, 12 and 22**, with the exception of reciting that the bone in which the void is formed is cancellous bone, which is compressed when the expandable structure **108** is expanded. However, the use of an expandable structure to compress cancellous bone was known at the time the invention was made. Specifically, Reiley et al. teaches the use of a "balloon for use in compressing cancellous bone... to form a cavity in the cancellous bone and to restore the original position of the outer cortical bone, if fractured or collapsed" (see Abstract). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of Marchosky by performing the method within cancellous bone because it is well known in the art, as taught by Reiley et al., to perform such a procedure in order to repair fractured or collapsed bone.

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese whose telephone number is 571-272-4804**. The examiner can normally be reached on Monday through Friday from 9:00 am until 5:00 pm.
16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR 
July 25, 2005

Henry Bennett
Supervisory Patent Examiner
Group 3700

